

By this amendment, Applicants have amended claim 1 to more precisely define Applicants' invention. New claim 15 has been added. No new matter is believed to be added by these amendments. Applicants respectfully submit that claims 1 and 9, as amended, and claims 2-8 and 10 - 14, dependant thereon, are patentable to Applicants over the prior art cited by the Examiner and the prior art of record. Additionally, new claim 15 is patentable to Applicants for at least the same reason as claims 1 and 9.

**1. Rejection Of Claims 1-14 Under 35 U.S.C. § 103(a)**

Reconsideration of rejected claim 1 is respectfully requested based on the foregoing amendments and the following remarks. Claim 1 recites a method of sealing a skin incision for performing a minimally invasive surgical procedure comprising providing a sealing device having a tube, wherein the proximal end of the tube has a larger diameter than the distal end, the tube including an inflatable membrane disposed within an inner bore of the tube. In the methods of the present invention, the smaller distal end of the tube of the sealing device is inserted through an incision in the body and advanced sufficiently to seal the edges of the incision against an outer surface of the tube.

Thus, the present invention is drawn to a method of sealing a skin incision for performing a minimally invasive procedure wherein an incision in the skin is sealed using a device such as described in Applicants' disclosure.

In contrast, Hillstead discloses a pressure-activated valve device for sealing a flow conduit. Applicants respectfully assert that the claims are not properly rejected over Hillstead, either separately or in combination with Hunt, because neither of the references teach or suggest the claimed methods. It is essential to note at the outset that the pending claims are directed to

methods, not devices. The rejections set forth in the Office Action would appear to indicate that the examiner relies on an “inherency” argument in asserting that claims 1-14 are obvious over Hillstead, either alone or in combination with Hunt. However, after reviewing Hillstead, it is plain that Hillstead is directed to devices sealing the inner lumen of a hemostasis valve, not to methods for sealing a skin incision for performing minimally invasive surgery as recited in claims 1-14 and new claim 15.

The law is clear that the mere disclosure of a device is not enough to constitute an obviousness rejection of a method claim. In the case of *Carnegie Steel Company, Ltd. v. Cambria Iron Company*, 185 U.S. 403 (1902), the U.S. Supreme Court considered this issue with regard to claims in a patent directed to a process for rendering the product of steel works uniform in composition. The Court considered a number of prior art references which were alleged to invalidate the patented claims. These references generally included furnaces for smelting metal ores, but none of the references disclosed the claimed method. In upholding the patent, the Supreme Court stated:

As hereinafter observed, a process patent can only be anticipated by a similar process. It is not sufficient to show a piece of mechanism by which the process *might* have been performed. (Emphasis original.)

*Id.* at 980. See also *In re Osplack*, 93 USPQ 306 (CCP 1952) (“The mere fact that there exists in the prior art a machine capable of carrying out a process does not in itself negative patentability of that process, . . .”)

In the present application, the claims are directed to methods for sealing a skin incision for performing a minimally invasive procedure. The step of “making an incision in

the body,” as recited in the claims, is not found in Hillstead. The step of “inserting said distal end of said sealing device through said incision,” as recited in the claims, is not found in Hillstead. The step of “advancing said sealing device through said incision to form a seal between said incision and said outer surface of said outer bore,” as recited in the claims, is not found in Hillstead. As stated by the Supreme Court in *Carnegie*, it is not sufficient for obviousness to show a prior art device by which the process *might* have been performed.

Further, Hillstead does not disclose all of Applicants’ structural limitations. Specifically, Applicants claim a sealing device comprising a “tube having a proximal end and a distal end . . . said proximal end having a larger outer diameter than said distal end.” In contrast, since Hillstead was not concerned with the problem of sealing the outer surface of his device within a skin incision, he discloses a uniform diameter housing which is not suited for sealing within a skin incision. Thus, the device of Hillstead cannot be “advanc[ed] . . . through said incision to form a seal between said incision and said outer surface of said outer bore.” Specifically, as the device of the present invention is advanced, the larger outer diameter of the proximal end of the device forms a seal with the edges of the incision. Thus, claims 1-14 are not properly rejected under 35 U.S.C. §103(a) as being unpatentable over Hillstead, either when viewed alone or in combination with Hunt.

Finally, claim 15 recites a method of sealing a seal incision for performing a surgical procedure including the steps of deflating the inflatable member sufficiently to allow passage of a surgical tool through said inner bore and performing a surgical procedure through the incision with the surgical tool. Thus, Claim 15 is patentable for the reasons given above as well as the additional reason that neither Hillstead nor Hunt disclose the step of performing a

surgical procedure using a surgical tool inserted through the inner bore of the sealing device.

## II. CONCLUSION

For the foregoing reasons, claims 1 - 15 of the instant application are in condition for allowance. If the Examiner has any additional questions or concerns, he is invited to contact Applicants' undersigned representative to resolve such issues to expedite the closing of prosecution on this application.

Please charge deposit account No. 12-2475 for any additional fees necessitated by the filing of these documents.

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Respectfully submitted,

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